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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CLIFTON A. ALFERNES,
JAI SHANKER RAMAN, and JOHN MELMOUTH POWER

Appeal 2008-4555
Application 10/809,962
Technology Center 3700

Decided: January 23, 2009

Before DONALD E. ADAMS, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal¹ under 35 U.S.C. § 134 from the Examiner's final rejection of claims 18, 19, 22, 23, 25, 26, 28, 34, and 35.² We have jurisdiction under 35 U.S.C. § 6(b).

¹ This Appeal was scheduled for hearing on January 14, 2009, which hearing was waived.

STATEMENT OF THE CASE

The claims are directed to a device for treating a disease of the heart.

Claim 18 is representative of the claims on appeal, and reads as follows:

18. A device for treating a disease of a heart, the device comprising:
- a jacket dimensioned to be placed on said heart with said jacket surrounding at least a lower portion of said heart and sized and shaped to snugly conform to an external geometry of said heart to constrain circumferential expansion of said heart during diastole and permit substantially unimpeded contraction of said heart during systole,
- said jacket having an open base end sized to be placed over said heart and to surround at least a valvular annulus of said heart and said jacket having a length sized to extend from said base end to an apex end sized to surround said heart near an apex of said heart, a direction between said base end and said apex end defining a longitudinal dimension;
- wherein said jacket is constructed from a biocompatible material selected to exhibit an amount of expansion in response to a force applied to said material by a heart in a first direction greater than an amount of expansion in response to said force applied to said material by a heart in a second direction; and

² Claims 36 and 37 are also pending, but have been indicated as being allowable (App. Br. 2).

said material oriented on said jacket with said first direction extending in a direction substantially aligned with said longitudinal dimension and said second direction aligned substantially transverse to said first direction;

whereby said jacket is more readily expandable in said longitudinal dimension than in a direction transverse to said longitudinal dimension.

The Examiner relies on the following evidence:

Field	US 1,682,119	Aug. 28, 1928
Mehler	US 2,376,442	May 22, 1945
Muller	US 3,452,742	Jul. 01, 1969
Matheson	US 4,466,331	Aug. 21, 1984
Wanat	US 5,839,842	Nov. 24, 1998

We affirm.

ISSUE

The Examiner finds that claims 18, 19, 22, 23, 28, and 35 are anticipated by Wanat; that claims 18, 19, 22, 23, 25, 28, 34, and 35 are anticipated by Mehler; and that claims 18, 19, 22, 23, 26, 34, and 35 are anticipated by Field as evidenced by Muller.

Appellants contend that the references relied upon by the Examiner have nothing to do with a device for placement on and treating a disease of the heart, and more specifically, do not teach structures that can constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole.

Thus, the issue on Appeal is: Have Appellants demonstrated that the Examiner erred in finding that the mesh structures of Wanat, Mehler, and Field would be inherently capable of constraining circumferential expansion of the heart during diastole and permitting substantially unimpeded contraction of the heart during systole?

FINDINGS OF FACT

FF1 The present invention is directed to a method and device for treating heart disease, such as congestive heart disease, and related valvular dysfunction (Spec. 1).

FF2 The invention includes a jacket made from a biocompatible material, wherein the jacket “has an internal volume dimensioned for an apex of the heart to be inserted into the volume and for the jacket to be slipped over the heart.” (Spec. 5.)

FF3 According to the Specification,

The jacket has a longitudinal dimension between upper and lower ends sufficient for the jacket to surround a lower portion of the heart with the jacket surrounding a valvular annulus of the heart and further surrounding the lower portion to cover at least the ventricular lower extremities of the heart. The jacket is adapted to be secured to the heart with the jacket surrounding at least the valvular annulus and the ventricular lower extremities. The jacket is adjustable on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and to permit unimpeded contraction of the heart during systole.

(*Id.*)

FF4 Figures 3 and 4 of the instant disclosure is reproduced below.

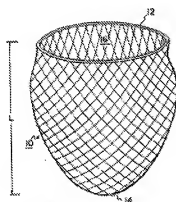


FIG. 3

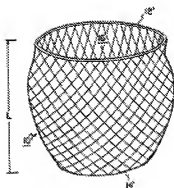


FIG. 4

Figures 3 and 4 are perspective views of two different embodiments of the cardiac constraint device, *i.e.*, the jacket of the present invention (*id.* at 6).

FF5 The jacket 10 is made from a knit material, having upper and lower end 12, 12' and 14, 14' (*id.* at 9). In the embodiment as shown in Figure 3,

the lower end 14 is closed, and in the embodiment shown in Figure 4, the lower end 14' is open (*id.*).

FF6 The Specification teaches:

To permit the jacket 10 to be easily placed on the heart H, the volume and shape of the jacket 10 are larger than the lower portion LP during diastole. So sized, the jacket 10 may be easily slipped around the heart H. Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (Fig. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole. Such shape represents a maximum adjusted volume. The jacket 10 constrains enlargement of the heart H beyond the maximum adjusted volume while preventing restricted contraction of the heart H during systole.

(*Id.* at 11.)

FF7 The Specification teaches further that the jacket is constructed from a knit, biocompatible material (*id.* at 12). Preferably, the knit is an atlas knit, which is a well known in the fabric industry (*id.*) In the atlas knit, the strands are interwoven to define a diamond-shaped open cell (*id.* at 13) The Specification teaches that the knit allows the jacket to expand even though the jacket itself is formed from generally inelastic fibers (*id.* at 12).

FF8 The Examiner rejects claims 18, 19, 22, 23, 28, and 35 under 35 U.S.C. § 102(e) as being anticipated by Wanat (Ans. 5). As Appellants do not argue the claims separately, we focus our analysis on claim 18, and

claims 19, 22, 23, 28, and 35 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

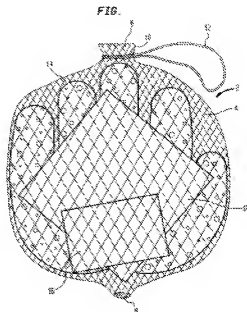
FF9 The Examiner finds that element 2 of Wanat forms a jacket with an open end 6, wherein the jacket may be formed from polyethylene, which is a biocompatible material (*id.*).

FF10 The strands of the jacket of Wanat are in a diamond pattern, and the Examiner finds that “that the jacket of Wanat [] . . . with the diamond pattern oriented as shown [in figure 1] is inherently capable of performing the other functions set forth in the functional language of . . . claim[s] 18, 23, and 28[.]” (*Id.* at 5-6.)

FF11 The Examiner also finds that the claims on appeal do not set forth any specific size for the jacket, but only define the size relative to an undefined heart, “therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims.” (*Id.* at 6.)

FF12 The Examiner cites the Specification for its teaching that the sizing of the jacket to snugly conform to the external geometry of the heart can be accomplished due to the knit construction of the jacket (FF6) to support the position “that ‘shaped’ as claimed represents a functional limitation provided for by the knit construction,” and that “the mesh structure of Wanat provides the same functional limitation.” (Ans. 6.)

FF13 The Figure of Wanat is reproduced below.



The figure shows a diamond shaped holding pouch containing a toilet bar and a sponge in the shape of a hand (Wanat col. 2, ll. 1-3). A drawstring 10 loops around open end 6 to close the open end (*id.* at ll. 13-15).

FF14 The “pouch 2 is formed of a diamond shaped mesh net 4 having a pocket with an open and closed ends 6, 8.” (*Id.* at col. 2, ll. 12-13.) The pouch is made from a polymeric material, such as polyethylene, and the mesh structure is polygonal, preferably diamond shaped, but may also be an irregular shape (*id.* at ll. 22-30).

FF15 The Examiner rejects claims 18, 19, 22, 23, 25, 28, 34, and 35 under 35 U.S.C. § 102(b) as being anticipated by Mehler (Ans. 7). As Appellants do not argue the claims separately, we focus our analysis on claim 18, and claims 19, 22, 23, 25, 28, 34, and 35 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

FF16 The Examiner finds that element 10 of Mehler reads on the jacket of claim 18, and as ends 11 and 12 may be knotted, the Examiner further finds that both ends may be open or closed (*id.*).

FF17 The Examiner finds further that the “diamond pattern allows for differential expansion of the jacket with the diamond pattern oriented as shown in figure 1 . . . is inherently capable of performing the other functions set forth in the functional language of the claim.” (*Id.*)

FF18 The Examiner also finds that the claims on appeal do not set forth any specific size for the jacket, but only define the size relative to an undefined heart, “therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims.” (*Id.*)

FF19 The Examiner notes that Mehler does not specifically teach the material used for the jacket except for teaching that the material would be the same as used for fish nets (*id.*). The Examiner finds, citing Matheson, that polyethylene is known to be such a material, and is also biocompatible (*id.*).

FF20 Finally, the Examiner cites the Specification for its teaching that the sizing of the jacket to snugly conform to the external geometry of the heart can be accomplished due to the knit construction of the jacket (FF6) to support the position “that ‘shaped’ as claimed represents a functional limitation provided for by the construction of Mehler.” (Ans. 8.)

FF21 Mehler is drawn to a tubular netting, wherein the netting may be used to lower dynamite or other explosive charges into a drill hole (Mehler col. 1, ll. 1-6).

FF22 Figures 1 and 2 of Mehler are reproduced below.

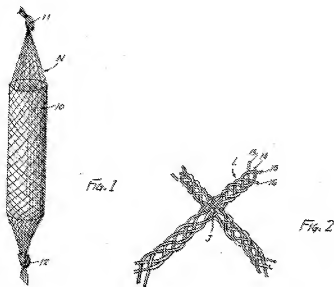


Figure 1 is a perspective of an explosive packaging showing the tubular netting, and Figure 2 is a “detailed view showing the threads of the braided links and woven joints in distended relation.” (*Id.* at col. 3, ll. 19-26). Reference 11 and 12 are drawn to the knots used to close the tube (*id.* at ll. 32-35).

FF23 The tubular netting of Mehler has meshes of fixed size, and has substantially smooth interior and exterior surfaces (*id.* at col. 2, ll. 16-25).

FF24 The Examiner rejects claims 18, 19, 22, 23, 26, 34, and 35 under 35 U.S.C. § 102(b) as being anticipated by Field as evidenced by Muller.

Again, as Appellants do not argue the claims separately, we focus our analysis on claim 18, and claims 19, 22, 23, 26, 34, and 35 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

FF25 The Examiner cites Field for teaching a metallic envelope, 2, which the Examiner finds reads on the jacket of claim 18 (Ans. 3).

FF26 According to the Examiner, Field teaches that the jacket may be made from German silver, and the Examiner cites Muller for teaching that a vascular spring guide may be made with German silver, thus demonstrating its biocompatibility (*id.* (citing Muller col. 5, ll. 44-52)).

FF27 The Examiner further notes the “material pattern shown in figure 3 and arranged as shown in figure 1 provides for a jacket having the particular expansion properties” as required by the functional language in the claims on appeal (*id.*).

FF28 The Examiner finds that the “interconnected rows of hinges provides for expansion and contraction in the circumferential direction without affecting the length of the envelope.” (*Id.*)

FF29 The Examiner finds further that the claims on appeal do not set forth any specific size for the jacket, but only define the size relative to an undefined heart, and that the shape of the envelope 2 “will be determined by what is placed in the envelope,” and that the pattern of the material allows for the shape to be adjusted (*id.*)

FF30 The Examiner cites the Specification for its teaching that the sizing of the jacket to snugly conform to the external geometry of the heart can be accomplished due to the knit construction of the jacket (FF6) to support the position “that ‘shaped’ as claimed represents a functional limitation provided for by the construction of Field.” (Ans. 4)

FF31 Field teaches a metallic mesh bag for retaining soap flakes (Field, col. 1, ll. 1-5).

FF32 Figures 1 and 3 of Field are reproduced below.

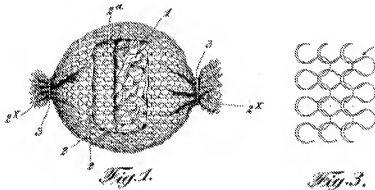


Figure 1 shows the knitted ribbon bag containing the chips of soap (*id.* at col. 1, ll. 29). Figure 3 shows a form of the metal ribbon fabric that may be used (*id.* at ll. 42-34).

FF33 Field teaches that the metallic mesh bag may be used analogously to a soap-containing wash cloth (*id.* at ll. 41-46).

FF34 According to Field, the “metal ribbons bent in the slidable loops required for stocking knit fabric afford natural scraping edges that are not too harsh,” noting that the ribbons may be 1/16 to 1/64 inch wide, to 1/500 to 1/100 inch thick (*id.* at ll. 58-67). The open ends of the tube, 2^x, are secured by wire or other suitable material (*id.* at ll. 92-94).

PRINCIPLES OF LAW

It is axiomatic that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed

invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). “[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). “When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art.” *Id.* at 709.

During prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *In re American Academy Of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). “An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.” *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989). Moreover, it is during prosecution that applicants have “the opportunity to amend the claims to obtain more precise claim coverage.” *American Academy*, 367 F.3d at 1364.

“A patent applicant is free to recite features of an apparatus either structurally or functionally.” *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997). However, to do so carries a risk, when “the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require

the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.” *Id.* (quoting *In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971); *see also Leggett & Platt, Inc. v. Vutek, Inc.*, 537 F.3d 1349, 1354-55 (Fed. Cir. 2008).

ANALYSIS

As to Wanat, Appellants argue that Wanat “does not teach or fairly suggest that its ‘netted mesh’ pouch is shaped to snugly conform to an external geometry of the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole.” (App. Br. 6.) In fact, Appellants assert, the shapes of the articles disclosed by the pouch of Wanat are very different in shape from a human heart (*id.*). Appellants assert further that Wanat merely teaches a receptacle to contain other components of the cleaning kit, and Wanat illustrates gaps and slack between the mesh pouch and the sponge, thus “the mesh pouch 2 . . . does not necessarily snugly conform to its contents.” (*Id.*)

According to Appellants, the Examiner’s reliance on the Specification (*see, e.g.*, FF6) is misplaced, as while the Specification teaches an embodiment wherein the volume and the shape of the jacket may be adjusted after placement is irrelevant, as the “jacket of the claimed invention must be sized and shaped to snugly conform to the external geometry of the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole.” (App. Br. 7.)

Appellants also argue that the Examiner has ignored the claim limitation that the jacket “constrain[s] circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole.” (*Id.* at 6-7.) Appellants assert that the Examiner has provided no support for the finding that a mesh bag will necessarily conform snugly to the external geometry of the heart, as well as “constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole.” (*Id.* at 7.) Appellants argue further that the heart is not uniform in diameter from the apex to the A-V groove, and with the claimed invention, “the jacket is specifically sized and shaped to snugly conform to the heart . . . heart during diastole and permit substantially unimpeded contraction of the heart during systole,” and Wanat does not teach or suggest a structure that can satisfy that requirement (*id.*).

Appellants argue further that Wanat “fails to mention any expansion characteristics of the disclosed ‘netted mesh’ pouch.” (*Id.*) Thus, Appellants assert, Wanat “fails to disclose or suggest a biocompatible material that exhibits an amount of expansion in response to a force applied in one direction by a heart greater than an amount of expansion in response to the force applied by the heart in a second direction.” (*Id.* at 7-8.) Appellants assert that is not a functional limitation, but rather “the requirements regarding the size and shape of the jacket and its differential expansion characteristics constitute claimed structural and functional features that clearly distinguish the claimed invention from generic mesh

structures such as that disclosed in the Wanat patent and the other cited references.” (*Id.* at 8.)

Appellants’ arguments are not convincing. Claim 18 is drawn to an apparatus, and not a method of using that apparatus. What is required by claim 18 is a jacket, wherein the jacket has at least one open end, is constructed of a biocompatible material, wherein the jacket is more readily expandable in the longitudinal direction than the transverse direction.

The jacket is of unspecified dimension as the claim does not specify the heart on which it is to be placed. All that is required is that the jacket be sized and shaped to perform the functional limitation that it snugly conform to an external geometry of said heart to constrain circumferential expansion of said heart during diastole and permit substantially unimpeded contraction of said heart during systole. Moreover, we interpret the claim as requiring that the jacket need only snugly conform to a part of the heart, and not the entire heart, based on the fact that the claim recites that the jacket snugly conform to *an* external geometry of the heart, along with the teaching of the Specification that the jacket can be shaped to the heart after it is placed on the heart (FF6).

The mesh bag of Wanat is made from a biocompatible material, polyethylene (FF9 and FF14), which is knit into a mesh with open diamond cells (FF10 and FF14), wherein the bag has one open end (FF13). The Specification teaches that the knit design of the jacket allows the jacket to expand even though the jacket itself is formed from generally inelastic fibers, wherein the knit preferably has a diamond-shaped open cell (FF7).

As the bag of Wanat has those properties, we agree with the Examiner that, in the absence of evidence to the contrary, it would meet the functional limitations of claim 18. We thus find that the preponderance of the evidence supports the Examiner, and the burden is properly shifted to Appellant that the mesh bag of Wanat would not meet the functional limitations of claim 18.

As to Mehler, Appellants argue that Mehler “has nothing to do with a device for placement on and treating a disease of the heart.” (App. Br. 14.) Appellants assert that Mehler teaches a “tubular netting ‘which is substantially uniform in diameter’” (*id.* (citing Mehler col. 2, ll. 41-44)), and thus “fails to teach or suggest a tubular netting that is shaped to snugly conform to the external geometry of a heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole.” (App. Br. 14.)

Again, Appellants’ arguments are not convincing, as claim 18 is drawn to an apparatus, and not a method of using the apparatus. The remainder of Appellants arguments as to Mehler were made above with respect to Wanat, and Appellants attention is drawn to the response to those arguments above.

As to Field, Appellants argue that Field “has nothing to do with a jacket for placement on and treating a disease of the heart, and cannot anticipate the rejected claims.” (App. Br. 9.) Appellants argue that Field “fails to disclose or suggest a jacket sized and shaped to snugly conform to an external geometry of the heart.” (*Id.*) Moreover, Appellants assert, the

Examiner does not address the requirement “that the jacket be sized and shaped to not only snugly conform to the external geometry of the heart, but also to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole.” (*Id.* at 10.) Appellants argue further that Field is silent on the expansion characteristics of the metallic mesh envelope, and thus does not teach such differential expansion characteristics in response to a force applied by the heart in different direction (*id.* at 10-11).

As we have noted, claim 18 is drawn to an apparatus, and not a method of using that apparatus. As we discussed with respect to Wanat, the Specification teaches that the knit design of the jacket allows the jacket to expand even though the jacket itself is formed from generally inelastic fibers (FF7). As the bag of Field is knit from silver ribbon, and is formed as slidable loops (FF28, FF34), we agree with the Examiner that, in the absence of evidence to the contrary, it would meet the functional limitations of claim 18.

Appellants assert that Muller does not establish that German silver is a biocompatible material, as the spring guide is intended to be removed once catheritization is complete (Reply Br. 4). Appellants argue moreover that Field’s envelope has “scraping edges,” that will not scar the surface of aluminum utensils of other metal surfaces, and thus, it does not follow that it would be capable of treating diseases of the heart (*id.* at 5).

These arguments are not convincing, as the Examiner has cited evidence in the form of Muller that German silver has been used for *in vivo* procedures, such as its use in forming a vascular spring (FF26). Appellants provide no evidence that German silver is not biocompatible, but merely present attorney argument in response to the evidence provided by the Examiner, and arguments of counsel cannot take the place of evidence in the record. *In re Scarbrough*, 500 F.2d 560, 566 (CCPA 1974). As to the scraping edges, Field teaches that the mesh bag may be used analogously to a wash cloth (FF33), and that the scraping edges are not too harsh (34), and thus it does not appear that the mesh bag of Field would not meet the functional limitations of claim 18.

The remainder of Appellants arguments as to Field were made above with respect to Wanat, and Appellants attention is drawn to the response to those arguments above.

CONCLUSIONS OF LAW

We thus find that Appellants have not demonstrated that the Examiner erred in finding that the mesh structures of Wanat, Mehler, and Field would be inherently capable of constraining circumferential expansion of the heart during diastole and permitting substantially unimpeded contraction of the heart during systole.

We thus affirm the rejection of claims 18, 19, 22, 23, 28, and 35 under 35 U.S.C. § 102(e) as being anticipated by Wanat; the rejection of claims 18, 19, 22, 23, 25, 28, 34, and 35 under 35 U.S.C. § 102(b) as being anticipated

by Mehler; and the rejection of claims 18, 19, 22, 23, 26, 34, and 35 under 35 U.S.C. § 102(b) as being anticipated by Field as evidenced by Muller.

TIME LIMITS

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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